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## SUBSTITUTE SPECIFICATION

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### A SURGICAL DEVICE

#### BACKGROUND OF THE INVENTION

#### FIELD OF THE INVENTION

*Entry*  
*m/s*

**[0001]** The present invention relates to a surgical device for use in minimally invasive surgery of the type using patient pneumoperitoneum and an access port.

#### DESCRIPTION OF RELATED ART

**[0002]** Minimally invasive surgery of this type is carried out having introduced gas into a patient's body cavity through an incision and sealed the incision with an access port. The access port enables laproscopic and hand or instrument assisted surgery to be performed.

**[0003]** A sleeve forming such a port is shown in WO-A-95/07056 entitled "Apparatus for use in surgery". The access port sleeve shown is used to create a controlled pressurized environment within the sleeve while allowing a surgeon's arm to pass through the sleeve. During surgery, gas is pumped into the patient's body cavity where the surgery is to be performed and the sleeve prevents gas escaping while allowing the surgeon to operate using minimally invasive surgery techniques. The application shows a sleeve having a flange at a distal end provided with adhesive for adhering the device to a patient's body or alternatively a mounting ring to surround the incision in a patient's body. While providing a suitable apparatus for performing such surgery the device described suffers from the principle disadvantage that in use, the sleeve protrudes upwardly from the patient and may interfere with the activities of the surgery team. Additionally, the sleeve must be sealed against the surgeon's upper forearm by clamping the device to the arm sufficiently tightly to avoid gas leak around the area of the seal. This presents the surgeon with a problem both in sealing the sleeve and in subsequent mobility.

**[0004]** A further problem associated with the use of sleeves of the kind described is that a phenomenon known as "tenting" may occur. "Tenting" means that when the sleeve is adhered to the patient's skin or to a surgical drape and gas is induced into the patient's

abdominal cavity, there is a tendency for the sleeve to fill with gas and to pull away from the patient.

**[0005]** United States Patent Specification No. US 5 514 133 discloses an endoscopic surgical apparatus for enabling a surgeon to access directly the surgical site during an endoscopic procedure. This apparatus includes an opening extending longitudinally through the apparatus and prior art is configured and dimensioned to receive a hand therethrough. A first plate engages against the outer surface of the abdominal wall. A second plate is spaced from the first plate and is movable between a first position and a second position wherein the second plate is in close cooperative alignment with the inner surface of the abdominal wall. An adjustment member is mounted to the second plate and actuates movement of the second plate between its first position and its second position. A first sealing member inhibits the flow of gas through said opening and is formed by a pair of overlapping seals. A flexible sleeve extends between the first and second plates and adjusts in length to accommodate various thicknesses of the abdominal wall. The sleeve also creates an access port for the passage of objects through the abdominal wall.

#### SUMMARY OF THE INVENTION

**[0006]** A surgical device for use in minimally invasive surgery of the type using an inflated body cavity accessible to a surgeon through an access port, defined by the device, surrounding an incision in a patient's body, the device having: body cavity engagement means for insertion into the incision to locate the device in position; fixing means for attaching the device to a patient's skin; a sleeve connectable between the body cavity engagement means and the fixing means; characterized in that the fixing means is a proximal ring; and the sleeve being adjustable by the positioning of the proximal ring; the positioning of the proximal ring retracting the sleeve to define an access port and create a seal between the incision and sleeve; the proximal ring having an associated connector ring for receiving additional seals or medical instruments; and sealing means, operating on the sleeve to prevent substantial leakage of gas from the body cavity on inflation when in an inoperative position and formed to mould about a substantial portion of a surgeon's hand or

surgical instrument on insertion in an operating position. Preferably, the body cavity engagement means is provided by a distal ring formed for insertion into the incision.

**[0007]** In one arrangement, the distal ring has an associated cuff valve operating on the internal faces of an impermeable film, the film being located between semi rigid actuates, the actuates in turn being secured in substantially parallel manner to a distal ends of the sleeve. Preferably the actuates are housed in opposing cuff, each cuff being formed by folding an end of a distal tube to form a pocket for reception of the actuate. Ideally the actuates incorporate a bio-compatible medical grade foam layer to generate tension between opposing faces of the film and to operate as a cushion between the actuates and objects inserted through the cuff valve.

**[0008]** In an alternative arrangement, the distal ring has an associated self-sealing valve. In one arrangement the fixing means incorporates adjustment means for modifying the length of the sleeve. This ensures that the fixing means, distal ring and valves are brought into close contact with the abdominal wall ensuring a good seal is maintained and that the device is firmly mounted in position.

#### BRIEF DESCRIPTION OF THE DRAWINGS

- [0009]** Fig. 1 is a front view of a surgical device in accordance with the invention;
- [0010]** Fig. 2 is a section view in the direction of the arrows A-A of the surgical device of Fig. 1;
- [0011]** Fig. 3 is an end view of the surgical device of Figs. 1 and 2;
- [0012]** Fig. 4 is a side view of an alternative self sealing valve forming part of a surgical device in accordance with the invention in an inoperative position;
- [0013]** Fig. 5 is a side view of portion of the valve shown in Fig. 4 in an operating position;

[0014] Fig. 6 is a side view of a further alternative self sealing valve forming part of a surgical device in accordance with the invention in an inoperative position;

[0015] Fig. 7 is a side view of portion of the valve shown in Fig. 6 in an operating position;

[0016] Fig. 8 is a side view of another self sealing valve forming part of a surgical device in accordance with the invention in an inoperative position; and

[0017] Fig. 9 is a side view of portion of the valve shown in Fig. 8 in an operating position.

#### DETAILED DESCRIPTION OF THE INVENTION

[0018] Referring to the drawings, and initially to Figs. 1 to 3 there is illustrated a surgical device according to the invention, indicated generally by the reference numeral 1. The surgical device 1 is formed for use in minimally invasive surgery of the type using an inflated body cavity indicated generally by the reference numeral 2. The cavity 2 is accessible to a surgeon through an access port, defined by a sleeve 4, passing through an incision in a patient's abdominal wall 3.

[0019] In more detail, the device 1 has a body cavity engagement means provided by a distal ring 5 for insertion into the incision to locate the device 1 in position. The distal ring 5 prevents the device from becoming detached from the body inadvertently and has an associated cuff valve 8 for sealing the sleeve 4 when not in use. The device 1 is held in position on the patient's skin out side the body by a fixing means provided in this case by a proximal ring 6. The distal ring 5 and proximal ring 6 ensure that the device 1 is securely fixed in position, both rings 5,6 surround the incision and the sleeve 4 passes through the incision connecting the rings 5 and 6. The proximal ring 6 has adjustment means provided by being rotatably mounted on the skin to modify the length of the sleeve 4. This ensures that the fixing means and the distal ring 5 are brought into close contact with the abdominal wall 3 thereby, ensuring a good seal is maintained and that the device 1 is firmly mounted in position.

[0020] The proximal ring 6 may have a connector ring 7 for receiving additional seals to prevent loss of pressure from the cavity 2. The connector ring 7 may also be used for holding or guiding medical instruments into position over, through or in the incision.

[0021] In use, an incision is made in the abdominal wall 3 and the distal ring 5 and associated cuff valve 8 is passed through the incision into the cavity 2. The cuff valve 8 operates by pressing together internal faces of a flexible gas impermeable film mounted between semi-rigid actuates. The actuates are arranged substantially parallel in folded ends of a distal tube forming pockets to hold them in tension. The actuates have a bio-compatible medical grade foam along a side to cause tension between opposing faces of the film and to act as a cushion for objects inserted into the valve. The distal ring 5 is moved when in the cavity 2 so that the ring 5 surrounds the incision. The distal ring 5 thus surrounds the cuff valve 8. The proximal ring 6 can then be rotated, adjusted in height or stretched to take up the material and surplus sleeve 4 on the proximal ring 6. When the distal ring 5 is drawn up to snugly engage the internal abdominal wall 3 surrounding the incision, the proximal ring 6 is attached to the patient's skin to fix the device 1 in position. When in position, the sleeve 4 passing between the portions of the abdominal wall 3 exposed by the incision retracts the incision sides creating a lumen or bore through which an object or hand can be passed. A seal is provided by the cuff valve 8.

[0022] When a surgeon wishes to gain access to the cavity 2 a hand or instrument is passed down through the sleeve 4. The outward pressure of the retracted sleeve 4 on the abdominal wall ensures that access is not restricted. The cuff valve 8 is easily operated by the surgeon to gain access to the cavity 2 and surgery can be performed. As an object is removed, the cuff valve 8 closes down sealing the cavity 2.

[0023] It will be noted that equivalent methods of dispensing and retracting slack sleeve material following positioning of the device may be used.

[0024] Alternative embodiments of the invention are now described in which the cuff valve is replaced with a variety of self-sealing valves, however, it will be understood that the operation of these valves is not dependent on the adjustment means described above.

Referring now to Figs. 4 and 5 there is illustrated a further surgical device in accordance with the invention indicated generally by the reference numeral 20, in which parts similar to those identified with reference to Figs. 1 to 3 are identified by the same reference numerals generally. In this embodiment the cuff valve 8 has been replaced by a self-sealing valve 18. The valve 18 incorporates elasticised filaments, which are biased toward a closed position or inoperative position (see Fig. 4). When a surgeon passes a hand or instrument between the filaments which run all around the end of the sleeve 4 they are forced out of position into an operating position as shown in Fig. 5. As filaments are used they accurately mould to the surface of the inserted object preventing loss of gas from the body cavity 2. The memory resident in these filaments returns the valve 18 to the inoperative position once the object is removed to re-seal the sleeve 4.

**[0025]** Figs. 6 and 7 show an alternative to the cuff valve 8 described above in relation to Figs. 1 to 3. In this alternative embodiment, a spring valve 28 provides the seal to the sleeve 4. The spring valve 28 is provided by mounting a member 27 within a pocket 29 of the sleeve 4. Tension in the spring valve 28 is provided by forming the member 27 to be longer than the pocket 29. Operation of this valve is identical to that described above.

**[0026]** A further alternative valve is shown in Figs. 8 and 9. In this embodiment the horseshoe valve is provided as a snap open / snap shut valve 38. When positioned as described above the valve 38 is actuated by a surgeon's hand or instrument to open or close the valve 38, by pivoting sprung members about a pivot point 39 between an operating position as shown in Fig. 8 and an inoperative position as shown in Fig. 9. The method of biasing the members may be provided in any suitable way and the closing pressure is such as to avoid damage to any tissue, which may become trapped.

**[0027]** A still further arrangement, the proximal ring may be adjusted in height by means of inserting compressible foam rings between the proximal ring and the abdominal wall. Alternatively, the sleeve may be made of an elastomer material which when the distal ring is inserted into the incision, stretches the elastomer sheet causing tension between the distal ring and the proximal ring.

[0028] It will be understood that the self-sealing valves described herein may be equally used as external proximal valves or as internal distal valves.

[0029] It will of course be understood that the invention is not limited to the specific details described herein, which are given by way of example only, and that various modifications and alterations are possible within the scope of the invention.